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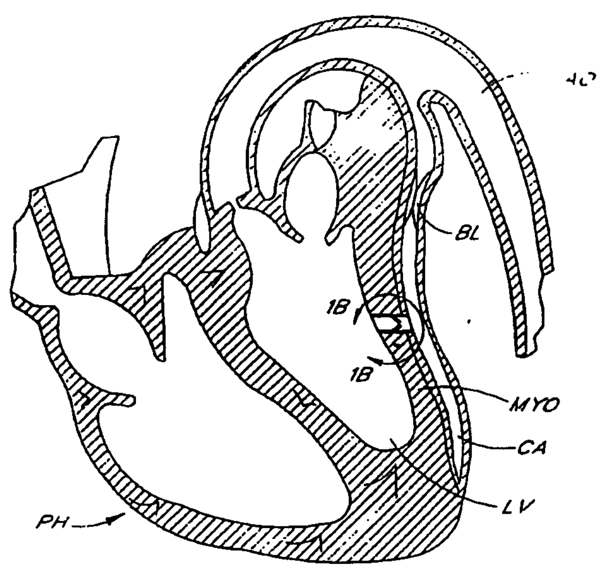

(57) Abstract

Disclosed is a conduit that provides a bypass around a stenosis or occlusion in a coronary artery. The conduit is adapted to be positioned in the myocardium to provide a passage for blood to flow from a heart chamber to a coronary artery, at a site distal to the blockage or stenosis in the coronary artery. The conduit has a one-way valve positioned therein to prevent the backflow of blood from the coronary artery into the heart chamber.

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TMR SHUNT WITH VALVE

Field of the Invention

This invention relates to apparatus and method for implanting a conduit to allow communication of fluids from one portion of a patient's body to another; and, more particularly, to a blood flow conduit to allow communication from a heart chamber to a vessel or vice versa, and/or vessel to vessel. Even more particularly, the invention relates to a left ventricular conduit and related conduit configurations for controlling the flow of blood through the conduit to achieve bypass of a stenosed or occluded coronary artery.

Background of the Invention

Coronary artery disease is a major problem in the U.S. and throughout the world. Coronary arteries as well as other blood vessels frequently become clogged with plaque, which at the very least impairs the efficiency of the heart's pumping action, and can lead to heart attack, arrhythmias, and death. In some cases, these arteries can be unblocked through noninvasive techniques such as balloon angioplasty. In more difficult cases, a bypass of the blocked vessel is necessary.

In a bypass operation, one or more venous segments are inserted between the aorta and the coronary artery. The inserted venous segments or transplants act as a bypass of the blocked portion of the coronary artery and thus provide for a free or unobstructed flow of blood to the heart. More than 500,000 bypass procedures are performed in the U.S. every year.

Such coronary artery bypass surgery, however, is a very intrusive procedure that is expensive, time-consuming and traumatic to the patient. The operation requires an incision through the patient's sternum (sternotomy), and that the patient be placed on a bypass pump so that the heart can be operated on while not beating. A vein graft is harvested from the patient's leg, and a delicate surgical procedure is required to piece the bypass graft to the coronary artery (anastomosis). Hospital stays subsequent to the surgery and convalescence are prolonged. Furthermore, many patients are poor surgical candidates due to other concomitant illnesses.

As mentioned above, another conventional treatment is percutaneous transluminal coronary angioplasty (PTCA) or other types of angioplasty. However, such vascular treatments are not always indicated due to the type of location of the blockage or stenosis, or due to the risk of emboli.

Thus, there is a need for an improved bypass system that is less traumatic to the patient.

Summary of the Invention

The preferred embodiments of the present invention address the need in the previous technology by providing a bypass system that avoids the sternotomy and other intrusive procedures normally associated with coronary bypass surgery. These embodiments also free the surgeon from the need to perform multiple anastomoses as is necessary in the current process.

The preferred device provides a conduit or shunt for diverting blood directly from the left ventricle of the heart to a coronary artery, at a point distal to the blockage or stenosis, thereby bypassing the blocked portion of the vessel. The conduit preferably comprises a tube adapted to be positioned in the myocardium and having a one way valve therein. The valve prevents the backflow of blood from the coronary artery into the left ventricle.

The conduit device is delivered through the coronary artery to a position distal the blockage or stenosis. At that position, the coronary artery, the myocardium and the wall of the left ventricle are pierced to provide an opening or channel completely through from the coronary artery to the left ventricle of the heart. The conduit is then positioned in the opening to provide a permanent passage for blood to flow between the left ventricle of the heart and the coronary artery, distal to the blockage or stenosis. The conduit is sized so that one open end is positioned within the coronary artery, while the other open end is positioned in the left ventricle. The hollow lumen of the conduit provides a passage for the flow of blood.

To prevent the backflow of blood from the coronary artery to the left ventricle of the heart, the conduit is provided with a one-way valve. The valve is preferably a windsock type valve, a flapper valve, a bi- or tricuspid valve, a ball valve, a valve formed from the myocardium itself, or a valve that opens and closes in response to the contraction and relaxation of the heart muscle, or in response to the electrical signals in the heart.

Brief Description of the Drawings

FIGURE 1A is a schematic, cross-sectional view of a human heart, showing a conduit in the myocardium of the heart for forming a bypass between the left ventricle and a coronary artery;

FIGURE 1B is an enlarged view of the bypass conduit of **FIGURE 1A**;

FIGURE 2 is a cross-sectional view of a windsock valve incorporated into a heart conduit in accordance with a preferred arrangement;

FIGURE 3 is a perspective view of a flapper valve incorporated into a heart conduit in accordance with a preferred arrangement;

FIGURE 4 is a perspective view of a tricuspid valve incorporated into a heart conduit in accordance with the preferred arrangement;

FIGURES 5A-D are cross-sectional views of a valve formed from the myocardium for use in conjunction with a heart conduit in accordance with a preferred arrangement;

FIGURES 6A-B are cross-sectional views of a valve that is activated by the contractions of the heart muscle for use in conjunction with a heart conduit in accordance with a preferred arrangement;

FIGURE 7 is a cross-sectional view of a valve that is activated by the electrical signals in the heart muscle for use in conjunction with a heart conduit in accordance with a preferred arrangement;

FIGURE 8 is a cross-sectional view of a ball valve incorporated into a heart conduit in accordance with a preferred arrangement;

FIGURE 9A-9B are cross-sectional views of a valve with spring mechanisms incorporated into a heart conduit;

FIGURES 9C-9D are cross-sectional views of a valve with a balloon mechanism incorporated into a heart conduit;

FIGURES 9E-9F are cross-sectional views of a valve with an internal motor incorporated into a heart conduit;

FIGURE 10A is a partial cross-sectional view of a ball and cage valve incorporated into a heart conduit;

FIGURE 10B is a cross-sectional view of a ball valve incorporated into a heart conduit having a narrower distal end;

FIGURE 10C is a cross-sectional view of a ball valve incorporated into a heart conduit having a smooth taper.

Detailed Description of the Preferred Embodiment

As is well known, the coronary artery branches off the aorta and is positioned along the external surface of the heart wall. Oxygenated blood that has returned from the lungs to the heart then flows from the heart to the aorta. Some blood in the aorta flows into the coronary arteries, and the remainder of blood in the aorta flows

on to the remainder of the body. The coronary arteries are the primary blood supply to the heart muscle and are thus critical to life. In some individuals, atherosclerotic plaque, aggregated platelets, and/or thrombi build up within the coronary artery, blocking the free flow of blood and causing complications ranging from mild angina to heart attack and death. The presence of coronary vasospasm, also known as "variant angina" or "Prinzmetal's angina," compounds this problem in many patients.

As used herein, the term "heart chamber" primarily refers to the interior, or lumenal, aspect of the left or right ventricle or the left or right atrium. The term "conduit," "stent," and "tube" herein refer to physical structures, preferably primarily artificial, that can be positioned between two or more chambers or vessels, to allow blood flow from one chamber or vessel to another. A "shunt" is any natural or artificial passage between natural channels, such as heart chambers or blood vessels. The conduit in the preferred arrangement can be made of a variety of materials, including various metals, such as nitinol, or plastics.

As used herein, the term "heart wall" comprises any one or more of the following portions or layers of the mammalian heart: the epicardium, myocardium, endocardium, pericardium, interatrial septum, and interventricular septum.

The principles of the present invention are not limited to left ventricular conduits, and include conduits for communicating bodily fluids from any space within a patient to another space within a patient, including any mammal. Furthermore, such fluid communication through the conduits is not limited to any particular direction of flow and can be antegrade or retrograde with respect to the normal flow of fluid. Moreover, the conduits may communicate between a bodily space and a vessel or from one vessel to another vessel (such as an artery to a vein or vice versa). Moreover, the conduits can reside in a single bodily space so as to communicate fluids from one portion of the space to another. For example, the conduits can be used to achieve a bypass within a single vessel, such as communicating blood from a proximal portion of an occluded coronary artery to a more distal portion of that same coronary artery.

In addition, the conduits and related methods can preferably traverse various intermediate destinations and are not limited to any particular flow sequence. For example, in one preferred embodiment of the present invention, the conduit communicates from the left ventricle, through the myocardium, into the pericardial space, and then into the coronary artery. However, other preferred embodiments are

disclosed, including direct transmyocardial communication from a left ventricle, through the myocardium and into the coronary artery. Thus, as emphasized above, the term "transmyocardial" should not be narrowly construed in connection with the preferred fluid communication conduits, and other nonmyocardial and even noncardiac fluid communication are preferred as well. With respect to the walls of the heart (and more specifically the term "heart wall"), the preferred conduits and related methods are capable of fluid communication through all such walls including, without limitation, the pericardium, epicardium, myocardium, endocardium, septum, etc.

The bypass which is achieved with certain preferred embodiments and related methods is not limited to a complete bypass of bodily fluid flow, but can also include a partial bypass which advantageously supplements the normal bodily blood flow. Moreover, the obstructions that are bypassed may be of a partial or complete nature, and therefore the terminology "bypass" or "occlusion" should not be construed to be limited to a complete bypass or a complete occlusion but can include partial bypass and partial occlusion as described.

The preferred conduits and related methods disclosed herein can also provide complete passages or partial passages through bodily tissues. In this regard, the conduits can comprise stents, shunts, or the like, and therefore provide a passageway or opening for bodily fluid such as blood. Moreover, the conduits are not necessarily stented or lined with a device but can comprise mere tunnels or openings formed in the tissues of the patient.

The conduits of the present invention preferably comprise both integral or one-piece conduits as well as plural sections joined together to form a continuous conduit. The present conduits can be deployed in a variety of methods consistent with sound medical practice including vascular or surgical deliveries, including minimally invasive techniques. For example, various preferred embodiments of delivery rods and associated methods are disclosed. In one embodiment, the delivery rod is solid and trocar-like. It may be rigid or semi-rigid and capable of penetrating the tissues of the patient and thereby form the conduit, in whole or in part, for purposes of fluid communication. In other preferred embodiments, the delivery rods may be hollow so as to form the conduits themselves (e.g., the conduits are preferably self-implanting or self-inserting) or have a conduit mounted thereon (e.g., the delivery rod is preferably withdrawn leaving the conduit installed). Thus, the

preferred conduit device and method for installation is preferably determined by appropriate patient indications in accordance with sound medical practices.

In order to restore the flow of oxygenated blood through the coronary artery, the preferred arrangement provides for the shunting of blood directly from the heart to a site in the coronary artery which is distal the blockage or stenosis.

Although the specification herein will describe the conduit primarily with reference to the left ventricle, the preferred arrangement can be used with any of the four heart chambers, and with any coronary artery, including the left main coronary artery, the right coronary artery, the left anterior descending artery, the left circumflex artery, the posterior descending artery, the obtuse marginal branch or a diagonal branch.

A tunnel or opening is formed through the wall of the coronary artery and the heart wall and into the left ventricle of the heart which lies beneath, or deep to, the coronary artery. A conduit is positioned in the opening to keep it open, and a one-way valve is positioned within the conduit to prevent blood from flowing back into the left ventricle of the heart from the coronary artery.

The conduit may be introduced into the heart wall in a variety of ways, including by a catheter threaded through the femoral artery into the aorta and thence into the left ventricle and, if necessary, the left atrium; or by a catheter threaded through the femoral vein into the inferior vena cava and thence into the right atrium and right ventricle. Alternatively, the conduit may be introduced through a surgical incision in chest wall (thoracotomy) or sternum (sternotomy).

Further details regarding conduits and conduit delivery systems are described in U.S. Patent Nos. 5,429,144 and 5,662,124.

The opening through the heart wall (including endocardium, myocardium, and epicardium) and coronary artery can be formed in a variety of ways, including by knife or scalpel, electrocautery, cryoablation, radiofrequency ablation, ultrasonic ablation, and the like. Other methods will be apparent to those of ordinary skill in the art.

Referring now to **FIGURES 1A** and **1B**, a coronary artery bypass is accomplished by disposing a conduit 12 (**FIGURE 1B**) in a heart wall or myocardium MYO of a patient's heart PH (**FIGURE 1A**). The conduit 12 preferably extends from the left ventricle LV of heart PH to a clogged coronary artery CA at a point downstream of a blockage BL to create a passageway 8 therethrough. Conduit 12 is preferably made

of a biocompatible material such as stainless steel or nitinol, although other materials such as Ti, Ti alloys, Ni alloys, Co alloys and biocompatible polymers may also be used. In one embodiment, conduit 12 has a one way valve 6 to allow blood to flow from the left ventricle LV to the coronary artery CA. Although the conduit 12 may elastically deform under the contractive pressure of the heart muscle during systole, the stent remains open to allow blood to pass from the patient's left ventricle LV into the coronary artery CA. During diastole, the blood pumped into coronary artery through passageway 8 is blocked by one-way valve 6 from returning to left ventricle LV.

One embodiment of the preferred arrangement is illustrated in **FIGURE 2**. The valve 10 incorporates a design similar to a windsock. The valve 10 is preferably formed from a biocompatible fabric-like material incorporated during the construction of the conduit 12. The high-pressure blood flow causes the valve 10 to open, while the backflow of blood catches the edges of the valve 10 and causes it to close, stopping the flow. The valve 10 can be positioned anywhere along the length of the conduit 12.

The valve 10 is preferably constructed from a biocompatible and very compliant fabric or other material that is pushed aside by the high forward blood pressure created from the contraction of the heart muscle, but opens to "catch" the back-flow of blood passing back through the conduit 12. The valve 10 is preferably constructed by incorporating the fabric or other material into the conduit 12 directly during its manufacture. This allows the valve 10 and conduit 12 to be introduced as a single unit.

Another embodiment of the preferred arrangement is illustrated in **FIGURE 3**. This valve 15 is a type of "flapper valve" that is built onto the end of the conduit 12 that is positioned in the coronary artery. The high-pressure blood flow opens the flap 14 and the backflow of blood causes the flap 14 to shut. This flap 15 is slightly larger than the conduit 12 inner diameter (ID) to accomplish this action and to ensure a proper seal. The valve 15 is preferably formed from the same material as the conduit 12 and the two are preferably introduced as a single unit. Alternatively, the valve 15 may be attached as a secondary operation once the conduit 12 is in place.

The third embodiment of the valve 16 is illustrated in **FIGURE 4**. This valve 16 is similar to a natural heart valve. A bi- or tricuspid arrangement of semi-circular spheres is forced open by the high-pressure flow and collapses back to prevent back-flow of blood through the conduit 12. This valve 16 is preferably made from the

same material as the conduit 12, or alternatively, from a thin biocompatible material that is built onto the conduit 12. Preferably, the valve 16 and the conduit 12 are manufactured together and introduced as a single unit. Alternatively, the valve 16 may be attached to the conduit 12 in a secondary operation once the conduit 12 is in place. The valve 16 may be placed at any location along the length of the conduit 12.

A further embodiment of the conduit is illustrated in **FIGURES 5A-D**. Here, the heart wall, which includes the myocardium MYO, lying between the coronary artery CA and the left ventricle of the heart LV, is cut using known techniques to form a passage through the myocardium MYO. **FIGURE 5A** shows the myocardium MYO after a cut or puncture has been made in it, with a free edge 17 shown at each margin of the cut or puncture. **FIGURE 5B** shows the myocardium MYO after a jagged or irregular surface 19 has been made with a cutting tool in the free edge 17 of the myocardium MYO. Such cutting tools may include knives, scalpels, lasers, radiofrequency probes, and other cutting tools known to those of skill in the art.

As illustrated in **FIGURE 5C**, two conduits, an upper or lower conduit, or a single conduit 18 having upper 18a and lower 18b components, is positioned in the passage. The myocardium MYO is left free between the two edges of the conduit 18 to form the valve 20. **FIGURE 5D** shows that during diastole, the edges or free portions of the myocardium MYO come together, closing the passage through the myocardium MYO. During systole, the free portions of the myocardium MYO can move away from one another as cardiac myofibrils contract, opening the passage through the myocardium MYO, as illustrated in **FIGURE 5C**. Thus, the heart muscle MYO itself can form at least part of the valve 20 in the conduit 18 to prevent the backflow of blood.

In another embodiment, the valve in the conduit may be controlled in response to the contractions of the heart. As illustrated in **FIGURES 6A** and **6B**, two conduits (**FIGURE 6A**), an upper conduit 20 and lower conduit 22, or a single conduit (**FIGURE 6B**) having upper moveable components 20 and lower moveable components 22, are positioned in the passage in the myocardium MYO between the left ventricle LV and the coronary artery CA. The conduit or conduits contain a valve 24, which is normally in a closed position, and an actuator 26, which is adapted to open the valve 24 in the conduit. During diastole, when the heart muscle MYO is relaxed, the two conduits or the two components of the conduit 20, 22 are positioned such that the valve 24 remains closed. During systole, the two conduits or

components 20, 22 are brought close together, such that the actuator 26 forces the valve 24 to open and allows for the passage of blood therethrough. Thus, the contractions of the heart muscle MYO control the valve 24 in the conduit to prevent the backflow of blood during part of the cardiac cycle, for example diastole.

The valve 24 may also be controlled by a hydrodynamic or electric pump or motor, which is responsive to the contractions of the heart, causing the valve 42 to open and close in response to various parts of the cardiac cycle.

A further embodiment of the preferred arrangement is illustrated in **FIGURE** 7. In this embodiment, electrical sensors 30 regulate the opening and closing of the valve 32 positioned within the conduit 34. The sensor 30 senses the electrical signals produced in the heart muscle, and causes the valve 32 to open during systole, and to close during diastole. This is accomplished by having an actuator 36 act in response to the electrical signals detected by the sensor 30, to open and close the valve 32. For example, the valve 32 can be biased in a closed position. When the sensor 30 detects the electrical signal that occurs during or immediately precedes systole, e.g., a QRS complex in the electrocardiogram, the sensor 30 signals the actuator 36 to force open the valve 32 and allow for the flow of blood therethrough. During diastole, the sensor 30 signals the actuator 36 to allow the valve 32 to close and prevent any backflow of blood. Alternatively, the valve 32 can be biased in an open position. When the sensor 30 senses diastole, such as through coordination with the P wave or PR interval in the electrocardiogram, or, for example, after the sensor delays for a predetermined time period after the QRS complex occurs in the electrocardiogram, it signals the actuator 36 to close the valve 32 and prevent the backflow of blood.

Another embodiment is illustrated in **FIGURE 8**. This valve 42 is a type of "ball valve" that is built into the conduit 40 that is positioned in the coronary artery. The high-pressure blood flow from the left ventricle LV to the coronary artery CA opens the valve 42 by moving the ball 44 away from the opening 46. The backflow of blood from the coronary artery CA to the left ventricle LV causes the ball 44 to seat against the opening 46, thereby closing the valve 42 and preventing the backflow of blood. The valve 42 and the conduit 40 are preferably introduced as a single unit.

Another embodiment is illustrated in **FIGURES 9A and 9B**. The conduit 12 has a valve 48 with one or more spring mechanisms 50 within its walls. In diastole **(FIGURE 9A)**, bloodflow pressure through the valve is relatively low, and the valve assumes a relatively closed position, impeding the passage of blood through the valve

48. In systole (**FIGURE 9B**), flow pressure through the valve is relatively high, and the valve 48 opens as the spring mechanism 50 contracts, to allow blood to flow through the valve 48.

Instead of a spring mechanism 50, the walls of the conduit 12 can have other mechanisms therein to allow differential flow during various parts of the cardiac cycle. For example, the valve 48 can have a gas- or liquid-filled balloon 52 in its wall, as shown in **FIGURES 9C** and **9D**. This balloon mechanism can contract (**FIGURE 9D**, during systole) or expand (**FIGURE 9C**, during diastole) in response to fluid pressure, to allow the valve 48 to open and close, respectively. Alternatively, the valve 48 can have an internal motor 54, shown in **FIGURES 9E** and **9F**, that opens and closes the valve 48 in response to electrical or mechanical signals from the heart during various parts of the cardiac cycle. For example, as illustrated in **FIGURE 9E**, during diastole, the motor preferably closes the valve 48, and during systole, the motor preferably opens the valve 48.

Another embodiment of the valve mechanism is illustrated in **FIGURE 10A**. The conduit 12 has a ball valve 60 that is of the ball-and-cage variety, for example, like the Starr-Edwards heart valve known to those of skill in the art. This valve 60 typically has a wire or mesh cage 62 with a ball 64 within it. The conduit is positioned within the myocardium MYO. During blood flow from the left ventricle LV to the coronary artery CA, the ball 64 moves toward the apex of the cage 62, permitting blood to flow around the ball 64 and through the conduit 12. During backflow of blood from the coronary artery CA to the left ventricle LV, the ball 64 moves toward the base of the cage 62 and seats thereon, fitting tightly onto the base of the cage 62, and blocking the flow of blood from the coronary artery CA to the left ventricle LV.

FIGURE 10B illustrates another embodiment wherein a ball 64 is provided within a conduit 12 that is wider at proximal end 56 facing the left ventricle, and narrower at distal end 58 facing the coronary artery. **FIGURE 10C** illustrates a similar embodiment wherein the conduit 12 has a gradual taper from the proximal end 56 to distal end 58. Like the embodiment of **FIGURE 10A**, during blood flow from the proximal end 56 to distal end 58, the ball 64 moves toward the coronary artery CA to allow blood flow around the ball through the conduit. In one embodiment, the cross-section of the conduit 12 in **FIGURES 10B** and **10C** is noncircular, for example elliptical, to allow blood to flow around the ball 64. During backflow from

the coronary artery CA to the left ventricle LV, the ball moves against the base 59 of the conduit to block flow of blood therethrough.

The present vascular conduit and valve system provides significant improvements in the present treatment of blockages and significant stenoses in the coronary artery. Although the invention has been described in its preferred embodiments in connection with the particular figures, it is not intended that this description should be limited in any way.

WHAT IS CLAIMED IS:

1. A coronary bypass conduit comprising:

a hollow tube having an interior and an exterior and adapted to be positioned in a wall of a heart between a coronary vessel and a heart chamber; and

an valve that limits blood flow to predominantly one direction, said valve being positioned within the interior of said tube.

2. The conduit of Claim 1, wherein said heart chamber is a left ventricle.

3. The conduit of Claim 1, wherein said heart chamber is a right ventricle.

4. The conduit of Claim 1, wherein said heart chamber is a left atrium.

5. The conduit of Claim 1, wherein said heart chamber is a right atrium.

6. The conduit of Claim 1, wherein said valve is a windsock valve.

7. The conduit of Claim 1, wherein said valve is a bicuspid valve.

8. The conduit of Claim 1, wherein said valve is a flapper valve.

9. The conduit of Claim 1, wherein said valve is a tricuspid valve.

10. The conduit of Claim 1, wherein said valve is a ball valve.

11. The conduit of Claim 1, wherein said valve is formed at least partly by said heart wall.

12. The conduit of Claim 1, wherein said valve is a valve that opens and closes in response to contraction and relaxation of said heart wall.

13. The conduit of Claim 1, wherein said valve is a valve that opens and closes in response to electrical signals in said heart.

14. A coronary bypass conduit comprising:

a hollow tube adapted to be positioned in a wall of a heart between a coronary artery and a heart chamber; and

means for permitting blood to flow in predominantly one direction through said tube, from said heart chamber to said coronary artery.

15. The conduit of Claim 14, wherein the means for permitting blood to flow in predominantly one direction is an artificial one-way valve in said tube.

16. The conduit of Claim 14, wherein the means for permitting blood to flow in predominantly one direction is a one-way valve, at least one wall of said valve being formed by said heart wall.

17. The conduit of Claim 16, wherein said valve is a windsock valve.

18. The conduit of Claim 16, wherein said valve is a bicuspid valve.

19. The conduit of Claim 16, wherein said valve is a flapper valve.

20. The conduit of Claim 16, wherein said valve is a tricuspid valve.

21. The conduit of Claim 16, wherein said valve is a ball valve.

22. The conduit of Claim 16, wherein said valve opens and closes in response to contraction and relaxation of said heart wall.

23. The conduit of Claim 16, wherein said valve opens and closes in response to electrical signals in said heart.

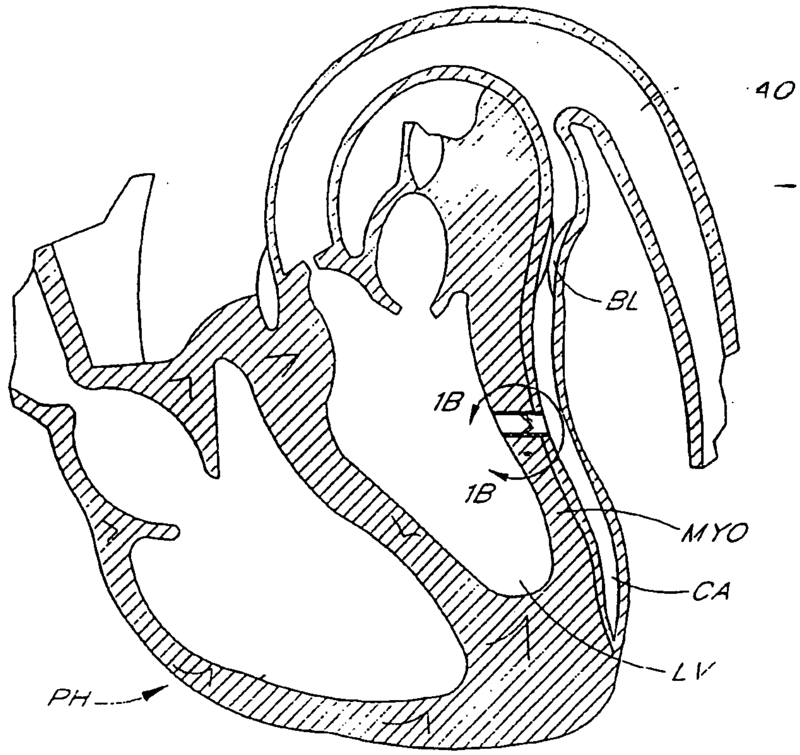

FIG. 1A

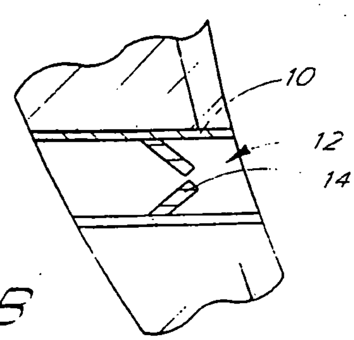

FIG. 1B

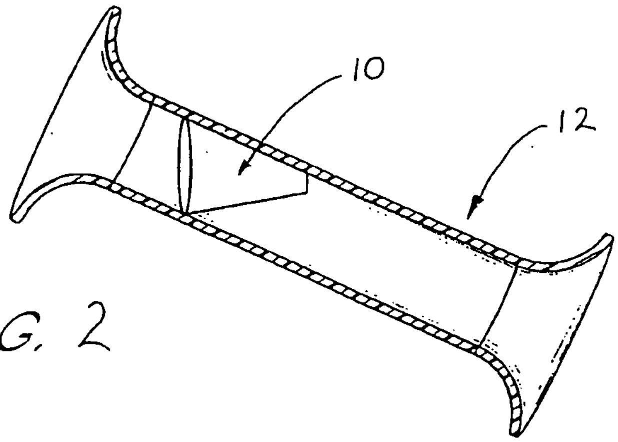

FIG. 2

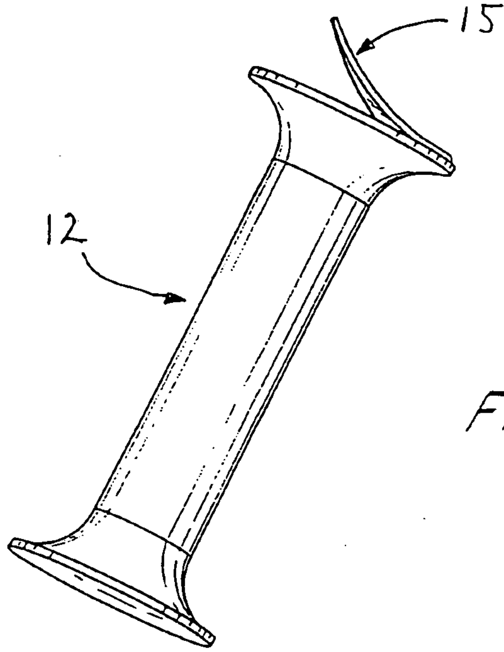

FIG. 3

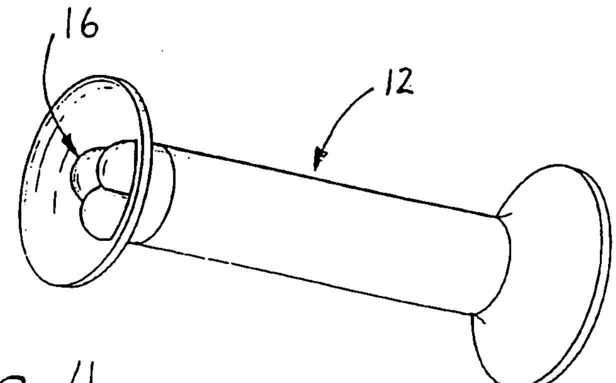

FIG. 4

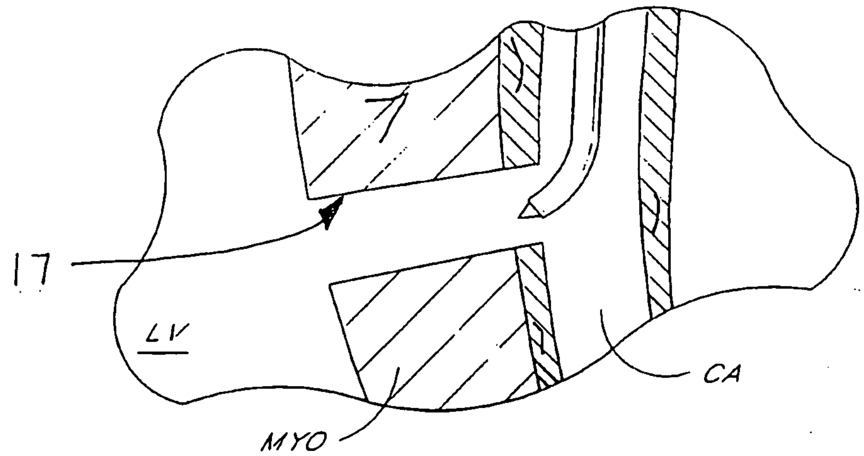

FIG. 5A

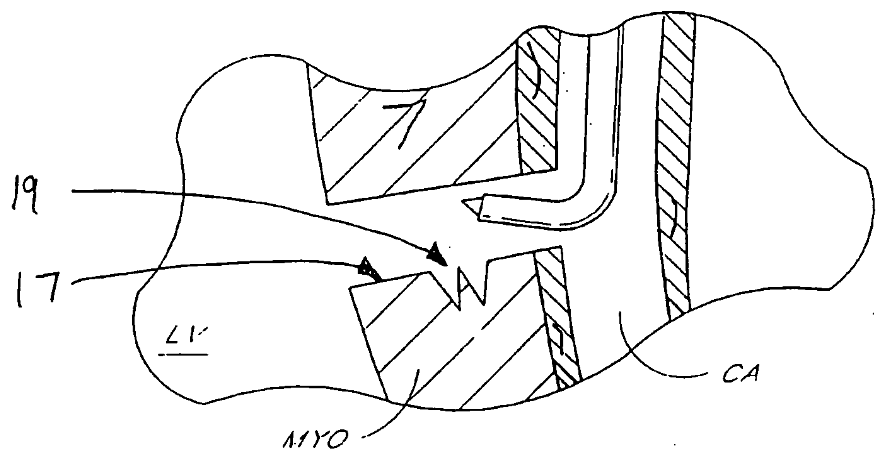

FIG. 5B

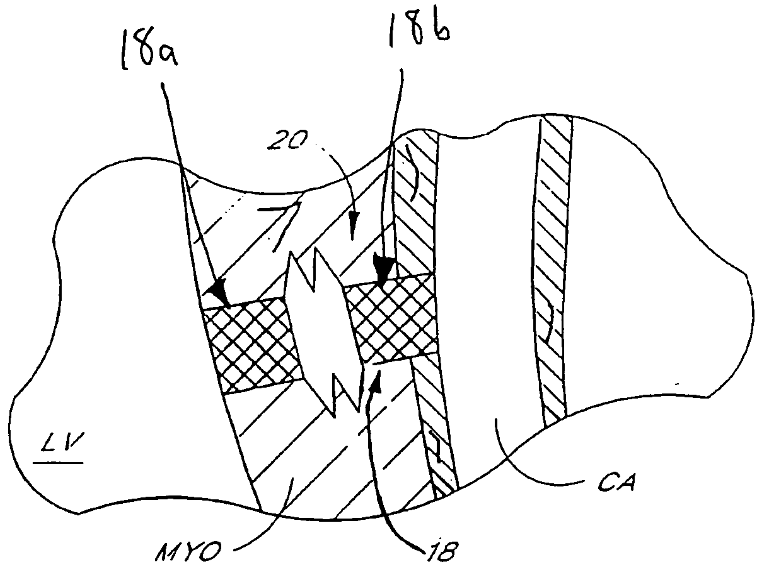

FIG. 5C

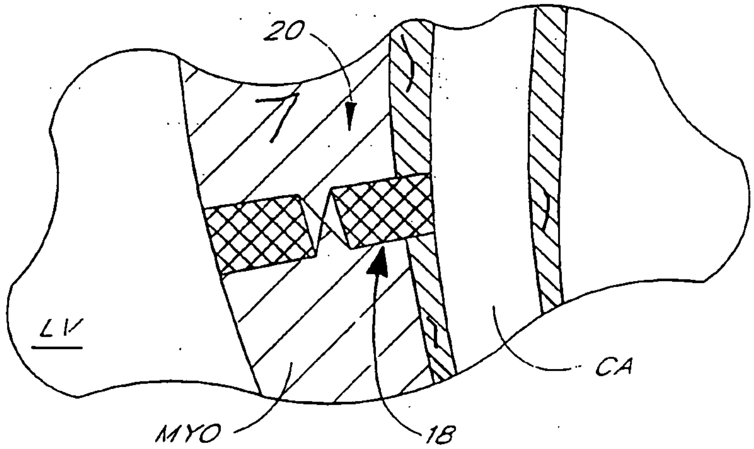

FIG. 5D

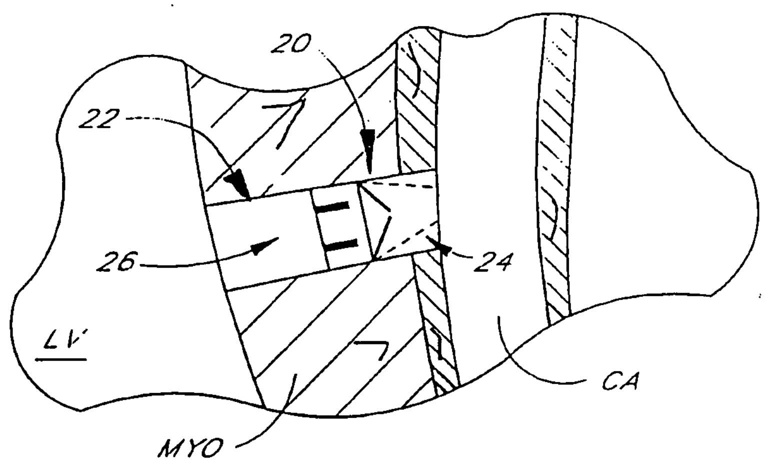

FIG. 6A

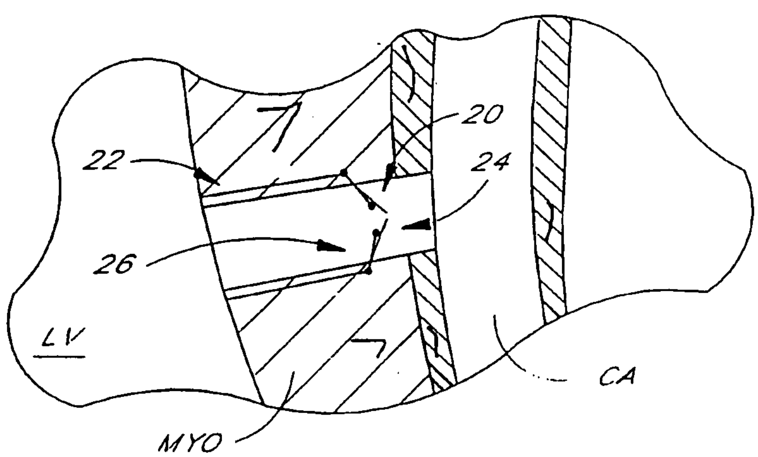

FIG. 6B

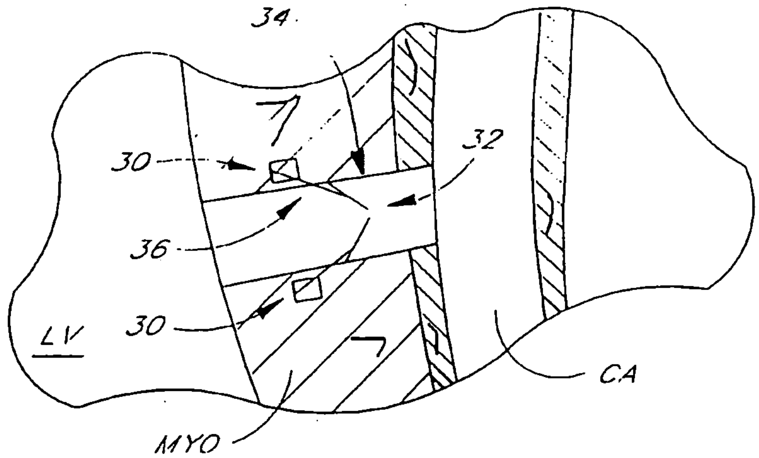

FIG. 7

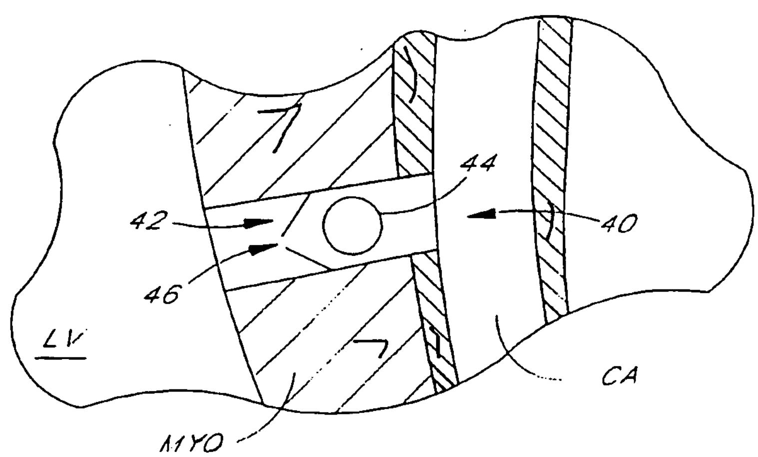

FIG. 8

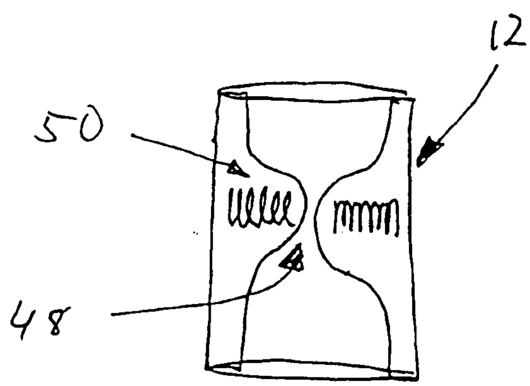

FIG 9A

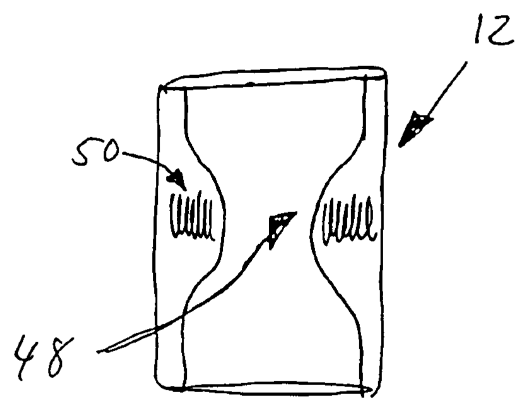

FIG 9B

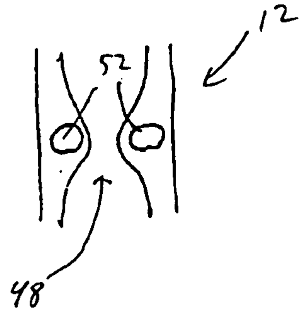

FIG. 9C

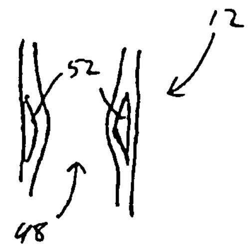

FIG. 9D

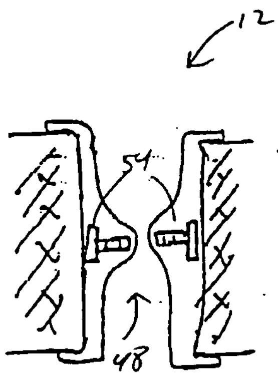

FIG. 9E

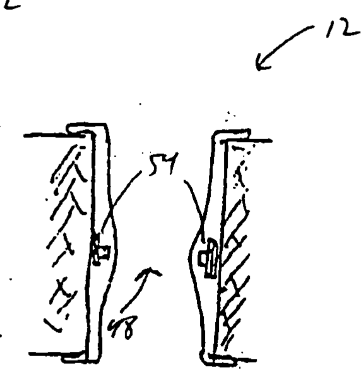

FIG. 9F

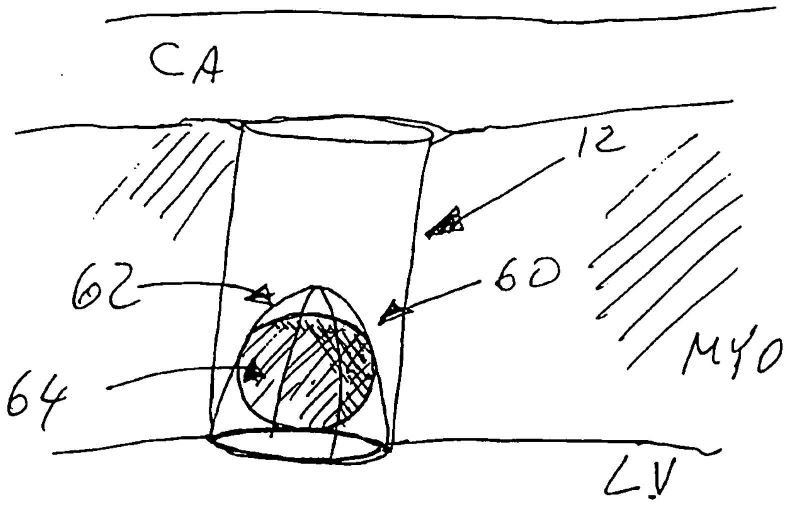

FIG 10A

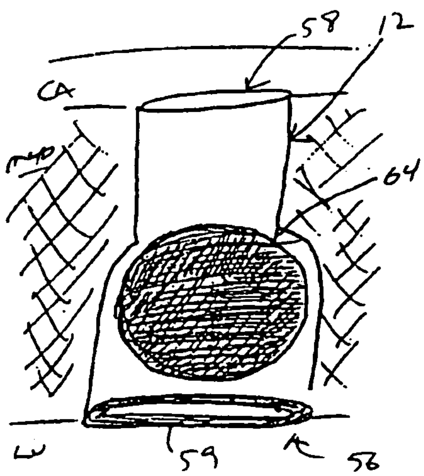

FIG. 10B

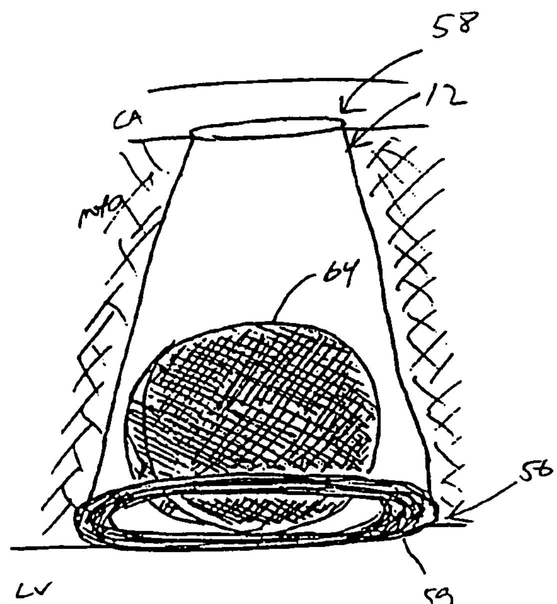

FIG. 10C

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/20775

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06 A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 08456 A (TRANSVASCULAR INC) 5 March 1998 (1998-03-05) figures 1-8 page 12, line 26 -page 14, line 6 page 25, line 16 -page 33, line 13	1-5,8, 11,12, 14-16, 19,22
Y		7,9,10, 13,18, 20,21,23
Y	US 4 655 773 A (GRASSI GINO) 7 April 1987 (1987-04-07) claim 1; figure 1	7,18
Y	US 5 713 950 A (COX JAMES L) 3 February 1998 (1998-02-03) abstract; figures 1-6	9,20

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
14 January 2000	21/01/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040 Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Mary, C

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International Application No
PCT/US 99/20775

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No
Y	US 3 911 502 A (BORETOS JOHN W) 14 October 1975 (1975-10-14) claim 1; figure 1	10,21
Y	US 4 979 955 A (SMITH ROBERT M) 25 December 1990 (1990-12-25) abstract; figures 1-4	13,23
X	US 5 655 548 A (SHMULEWITZ ASCHER ET AL) 12 August 1997 (1997-08-12) figures 4-6 column 6, line 7 -column 7, line 6	1-5,12, 14,22
A		6-11, 15-21
X	WO 97 32551 A (ENERGY LIFE SYSTEMS CORP) 12 September 1997 (1997-09-12) figure 6 page 5, line 2 -page 6, line 2 page 7, line 12 - line 26	1,14
P,X	US 5 830 222 A (MAKOWER JOSHUA) 3 November 1998 (1998-11-03) column 5, line 38 - line 49	1-5,12, 14,15,22
P,X	WO 99 36001 A (HEARTSTENT CORP) 22 July 1999 (1999-07-22) page 3, line 3 - line 29 page 4, line 5 - line 24	1-5,12, 14,22
A	US 5 487 760 A (VILLAFANA MANUEL A) 30 January 1996 (1996-01-30) abstract; figures 1,2	1,13,14, 16,23

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PCT/US 99/20775

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